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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-345]

**Schedules of Controlled Substances: Placement of Five Synthetic Cannabinoids into
Schedule I**

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) proposes placing five synthetic cannabinoids 1-pentyl-3-(1-naphthoyl)indole (JWH-018), 1-butyl-3-(1-naphthoyl)indole (JWH-073), 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200), 5-(1,1-dimethylheptyl)-2-(3-hydroxycyclohexyl)-phenol (CP-47,497), and 5-(1,1-dimethyloctyl)-2-(3-hydroxycyclohexyl)-phenol (cannabicyclohexanol, CP-47,497 C8 homologue) including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into Schedule I of the Controlled Substances Act (CSA). This proposed action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking.

DATES: DEA will permit interested persons to file written comments on this proposal pursuant to 21 CFR 1308.43(g). Electronic comments must be submitted and written comments must be postmarked on or before [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket

Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

Interested persons, defined as those “adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),”¹ may file a request for hearing or waiver of participation pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45. Requests for hearing and waivers of participation must be received on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-345” on all electronic and written correspondence. DEA encourages all comments be submitted electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this document and supplemental information to this proposed rule are also available at the <http://www.regulations.gov> website for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to www.regulations.gov will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/OD, 8701 Morrisette Drive, Springfield, VA 22152. All requests for hearing and waivers of participation must be sent to Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: Alan G. Santos, Associate Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 307-7165.

¹ 21 CFR 1300.01.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the "For Further Information" paragraph.

Request for Hearing or Waiver of Participation in Hearing

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking “on the record after opportunity for a hearing.” Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (5 U.S.C. 556 and 557) and 21 CFR 1308.41. Pursuant to 21 CFR 1308.44(a) and (c), requests for hearing and waivers of participation may be submitted only by interested persons, defined as those “adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).” Requests for hearing must conform to the requirements of 21 CFR 1308.44(a) and 1316.47. A request should state, with particularity, the interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c), including a written statement regarding the interested person’s position on the matters of fact and law involved in any hearing.

Please note that pursuant to 21 U.S.C. 811(a), the purpose and subject matter of the hearing is restricted to “(A) find[ing] that such drug or other substance has a potential for abuse, and (B) mak[ing] with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed...” Requests for hearing and waivers of participation in the hearing should be submitted to DEA using the address information provided above.

Legal Authority

The DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act and the Controlled Substances Import and Export Act (21 U.S.C. 801-971), as amended (hereinafter, “CSA”). The implementing regulations for these statutes are found in Title 21 of the Code of

Federal Regulations (CFR), parts 1300 to 1321. Under the CSA, controlled substances are classified in one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances by statute are found at 21 U.S.C. 812(c) and the current list of scheduled substances are published at 21 CFR Part 1308.

The CSA permits these initial schedules to be modified by providing that scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of HHS, or (3) on the petition of any interested party. 21 U.S.C. 811(a). The Attorney General may, by rule, “add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed...”

Background

On November 24, 2010, DEA published a Notice of Intent² to temporarily place five synthetic cannabinoids into Schedule I pursuant to the temporary scheduling provisions of the CSA: 1-pentyl-3-(1-naphthoyl)indole (JWH-018), 1-butyl-3-(1-naphthoyl)indole (JWH-073), 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200), 5-(1,1-dimethylheptyl)-2-(3-hydroxycyclohexyl)-phenol (CP-47,497), and 5-(1,1-dimethyloctyl)-2-(3-hydroxycyclohexyl)-phenol (cannabicyclohexanol, CP-47,497 C8 homologue). 75 FR 71635. Following this, on March 1, 2011, the Administrator published a Final Order in the Federal Register amending 21 CFR 1308.11(g) to temporarily place the five synthetic cannabinoids into Schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 76 FR 11075. This Final

² This Notice of Intent was corrected on January 13, 2011. 76 FR 2287.

Order, which became effective on the date of publication, was based on findings by the Administrator that the temporary scheduling of the five synthetic cannabinoids was necessary to avoid an imminent hazard to the public safety. The CSA (21 U.S.C. 811(h)(2)) requires that the temporary scheduling of a substance expire at the end of one year from the date of issuance of the order. However, if proceedings to schedule a substance pursuant to 21 U.S.C. 811(a) are pending, the temporary scheduling of a substance may be extended for up to six months. Under this provision, the temporary scheduling of the cannabinoids, which would expire on February 29, 2012, may be extended to August 29, 2012. This extension is being ordered by the Administrator in a separate action.

As described in the March 1, 2011 Final Order, a “cannabinoid” is a class of chemical compounds in the marijuana³ plant that are structurally related. The cannabinoid Δ^9 -tetrahydrocannabinol (THC) is the primary psychoactive constituent of marijuana. “Synthetic cannabinoids” are a large family of chemically unrelated structures functionally (biologically) similar to THC, the active principal of marijuana.

The emergence of these five synthetic cannabinoids represents a recent phenomenon in the U.S. designer drug market. Numerous products, marketed under the guise being "herbal incense," with trade names such as “Spice” and “K2” have conclusively been found to contain these five substances. These products are manufactured by spiking plant material with the synthetic cannabinoids and then distributed in a way that poses dangerous consequences to the consumer. Marketed as "legal" alternatives to marijuana, these products are being abused for their psychoactive properties and are packaged without information as to their health and safety risks.

³ Note that “marihuana” is the spelling originally used in the Controlled Substances Act (CSA). This document uses the spelling that is more common in current usage, “marijuana.”

Proposed Determination to Schedule Five Synthetic Cannabinoids

This NPRM proposes the permanent scheduling of JWH-018, JWH-200, JWH-073, CP-47,497 and cannabicyclohexanol pursuant to 21 U.S.C. 811(a)(1). On June 21, 2011, DEA requested a scientific and medical evaluation and scheduling recommendation from the Assistant Secretary of HHS for each of the five synthetic cannabinoids pursuant to 21 U.S.C. 811(b). Upon receipt and evaluation of the scientific and medical evaluation and scheduling recommendations from the Assistant Secretary,⁴ DEA concluded its analysis of all other relevant data for the proposal to place JWH-018, JWH-200, JWH-073, CP-47,497 and cannabicyclohexanol into Schedule I of the CSA.

Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in the scheduling decision. Please note that both the DEA and HHS analyses are available under “Supporting and Related Material” of the public docket for this proposed rule at www.regulations.gov under docket number DEA-345.

1. The Drug’s Actual or Relative Potential for Abuse: The abuse potential of the five synthetic cannabinoids under evaluation is associated with their ability to evoke cannabinoid-like subjective effects similar to those evoked by the Schedule I cannabinoid delta-9-tetrahydrocannabinol (THC).

The legislative history of the CSA provides four factors to consider in determining whether a particular drug or substance has potential for abuse:⁵

- i. There is evidence that individuals are taking the drug or other substance in

⁴ DEA received separate Evaluations and Recommendation documents from HHS with respect to each of the five synthetic cannabinoids. HHS recommended Schedule I placement for each of these five substances on the following dates: 1-pentyl-3-(1-naphthoyl)indole (JWH-018) (January 5, 2012); 1-pentyl-3-(1-naphthoyl)indole (JWH-073) and 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200) (February 6, 2012), 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497) and 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol) (February 13, 2012).

amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or

ii. There is significant diversion of the drug or substance from legitimate drug channels; or

iii. Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or

iv. The drug is a new drug so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that the drug or other substance will have the same potential for abuse as such drugs, thus making it reasonable to assume that there may be significant diversion from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

With respect to the first factor, a number of case reports and case series (article grouping several case reports) have shown that individuals are taking these substances and products containing these substances in amount sufficient to induce toxic effects similar to those induced by marijuana such as anxiety, tachycardia and hallucinations. Severe toxic effects including seizures, tachyarrhythmias, extreme anxiety leading to suicide and the precipitation of psychotic episodes have also been reported following abuse of these substances or products containing these substances.

⁵ Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91-1444, 91st Cong., Sess. 1 (1970); 1970 U.S.C.A.N. 4566, 4601.

In considering evidence of significant diversion of the drug or substance from legitimate drug channels under the second factor, it must be noted that as of March 1, 2011, these synthetic cannabinoids have been temporarily controlled as Schedule I substances and thus have not been legally available unless for research purposes. The National Forensic Laboratory Information System (NFLIS) details over 5,450 reports from state and local forensic laboratories identifying JWH-018, JWH-073, JWH-200, CP-47,497 or cannabicyclohexanol in drug related exhibits for a period from January 2009 to December 2011 from 39 states. The System to Retrieve Information from Drug Evidence (STRIDE) also details reports from federal forensic laboratories identifying JWH-018, JWH-073, and JWH-200 in drug related exhibits for a period from January 2009 to December 2011.

For the third factor, there is no currently accepted medical use for any of the five synthetic cannabinoids, and, outside of an extremely limited research setting, no medical practitioner is currently licensed by law to administer them. Thus, with no accepted medical use or administering practitioners, any individuals currently taking using products containing JWH-018, JWH-073, JWH-200, CP-47,497 or cannabicyclohexanol are doing so on their own initiative without medical advice from a practitioner licensed to administer those substances.

Related to the fourth factor, HHS states that JWH-018, JWH-073, JWH-200, CP-47,497 and cannabicyclohexanol are cannabinoids with a potential for abuse similar to the Schedule I substances marijuana and THC. These synthetic cannabinoids appear to be marketed solely for abuse of their marijuana-like activity and because, prior to the March 1, 2011 Final Order, they were not controlled under the CSA. As such, commerce involving these synthetic cannabinoids can only be for the purposes of abuse and escaping the regulatory and criminal penalties of the CSA that pertain to marijuana.

JWH-018, JWH-200, JWH-073, CP-47,497 and cannabicyclohexanol have agonist properties at the CB1 receptor. The CB1 receptors are thought to be responsible for the euphoric and psychoactive effects of THC and related cannabinoids.

Drug discrimination is a method in which laboratory animals indicate whether a test drug produces physical or psychic perceptions similar to those produced by a known drug of abuse. Drug discrimination studies in rats suggest that JWH-018, JWH-200, JWH-073, CP-47,497, and cannabicyclohexanol have similar subjective effects as THC, while numerous anecdotal self-reports, as well as case reports and case series substantiate that these substances and their associated products are abused by humans for their hallucinogenic effects. An indication of the extent of such abuse may be found in the results of the 2011 Monitoring the Future survey of high schools students, where 1 in 9 high school seniors (11.4%) reported having used “synthetic marijuana” (products often containing synthetic cannabinoids) in the past year. These statistics make it one of the most frequently mentioned among high school seniors, second only to marijuana. Additionally, while products containing synthetic cannabinoids appear to produce subjective effects similar to marijuana, they are dissimilar to other licit and illicit drugs.

As evidence of abuse on the national scale, State public health and poison centers have issued warnings in response to adverse health effects associated with abuse of herbal incense products containing these synthetic cannabinoids. These adverse effects included tachycardia, elevated blood pressure, unconsciousness, tremors, seizures, vomiting, hallucinations, agitation, anxiety, pallor, numbness and tingling. This is in addition to the numerous public health and poison centers which have similarly issued warnings regarding the abuse of these synthetic cannabinoids and their associated products, and the ban on the use of these synthetic cannabinoids by military personnel issued in response to reported instances of abuse by active

personnel.

2. Scientific Evidence of the Drug's Pharmacological Effects, If Known: In their recommendations for the placement of the five synthetic cannabinoids, HHS states that in vitro and preclinical studies suggest that the pharmacological effects of JWH-018, JWH-200, JWH-073, CP-47,497 and cannabicyclohexanol are similar to those of THC.

The CB1 receptors are thought to be responsible for the euphoric and psychoactive effects of THC and related cannabinoids. JWH-018, JWH-200, JWH-073, CP-47,497 and cannabicyclohexanol have agonist properties at the CB1 receptor.

Animal studies also provided evidence of cannabinoid-like pharmacological effects of these synthetic cannabinoids. JWH-018, JWH-200, CP-47,497 and cannabicyclohexanol were shown to be active in all four parameters of the mouse tetrad, a well-established paradigm for evaluating substances for cannabimimetic properties, while JWH-073 was only tested, and shown to be active, in three of the four parameters of the tetrad test. JWH-018, JWH-200, JWH-073, CP-47,497 and cannabicyclohexanol substitute fully for the discriminative stimulus effects of THC in laboratory animals, suggesting that they are likely to have similar subjective effects as THC, the main active ingredient of marijuana.

3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance:

The appearance of these substances in the designer drug market can be traced to the initial forensic laboratory confirmation in mid-December 2008. A commercial laboratory in Frankfurt, Germany announced the identification of JWH-018 in samples of herbal incense and others were identified shortly after this initial determination.

These five cannabinoid substances have been termed ‘synthetic’ or ‘non-classical’ because they are agonists at the CB1 receptor but are structurally distinct from naturally occurring cannabinoids.

HHS has confirmed to DEA in a letter dated November 22, 2010, that there are no Investigational New Drug Applications (INDs) or New Drug Applications (NDAs) for these synthetic cannabinoids. DEA is also not aware of any accepted medical use for these five synthetic cannabinoids.

4. Its History and Current Pattern of Abuse: Synthetic cannabinoids have been developed over the last 30 years to investigate their cannabimimetic properties and as research tools to investigate the cannabinoid systems (Huffman *et al.*, 1994; Wiley *et al.*, 1998). Trafficking of synthetic cannabinoids was first reported in the United States in a December 2008 encounter, where a shipment of ‘Spice’ was seized and analyzed by U.S. Customs and Border Patrol in Dayton, Ohio. Around the same time, in December 2008, JWH-018 and cannabicyclohexanol were identified by German forensic laboratories (EMCDDA, 2009).

JWH-018, JWH-073, JWH-200, CP-47,497, and Cannabicyclohexanol have been found alone and found laced on products that are marketed as herbal incense. The abuse of these substances and their associated products for their psychoactive effects has been widely reported and their popularity has spread rapidly since December 2008. The NFLIS has detailed over 5,450 reports from state and local forensic laboratories identifying JWH-018, JWH-073, JWH-200, CP-47,497 and/or cannabicyclohexanol in drug related exhibits for a period from January 2009 to December 2011 from 39 states. Prior to being temporarily placed in Schedule I on March 1, 2011, these products were promoted as legal alternatives to marijuana, were widely

available over the Internet, and were found to be sold in gas stations, convenience stores, tobacco and head shops to all populations.

As of January 13, 2012, forty-eight states in the U.S. as well as numerous local jurisdictions and countries have controlled at least one of these five synthetic cannabinoids.

5. The Scope, Duration, and Significance of Abuse: HHS states that the current scope and duration of use of the synthetic cannabinoids is likely underestimated because of the lack of widely available toxicological methods to identify its use using routine analyses (Peters and Martinez-Ramirez 2010). Additionally, since these substances were never intended for human consumption, minimal information exists as to the health implications resulting from exposure to these substances (Griffiths et al., 2010; Vardakou et al., 2010). As forensic procedures and toxicology screens are being developed, the amount of information concerning these substances and the associated products is increasing.

The abuse of synthetic cannabinoids has been associated with both acute and long-term public health and safety concerns. In the past year, increased exposure incidents have been documented by poison control centers in the United States. As of December 31, 2011, the American Association of Poison Centers (AAPCC) has reported receiving 9,992 calls corresponding to products purportedly laced with synthetic cannabinoids. The calls represented exposed individuals from all 50 states and the District of Columbia, as well as a few calls regarding exposed individuals in Puerto Rico, U.S. Territories, foreign countries, and a category identified as “overseas/US military/diplomatic.” Several of these exposures were confirmed to involve JWH-018 (141), and JWH-073 (12).

The increased abuse of these synthetic cannabinoids in the United States is supported by an increasing number of encounters by law enforcement. Over the past year in the United States

there has been a significant increase in availability, trafficking and abuse of these substances as evident from the increasing number of encounters reported by forensic laboratories (NFLIS and STRIDE data). Product manufacturing and synthesis laboratories have been discovered, and laboratories have been found manufacturing products by lacing plant material with synthetic cannabinoids.

6. What, if any, Risk There is to the Public Health: Law enforcement, military, and public health officials have reported exposure incidents that demonstrate the dangers associated with these substances to both the individual abusers and other affected individuals. Two suicides, one also involving a murder, have been linked to the abuse of synthetic cannabinoids (law enforcement communication to DEA). Warnings regarding the dangers of synthetic cannabinoid abuse and associated products have been issued by numerous state public health departments and poison centers and private organizations. Detailed product analyses describe variations in the amount and type of synthetic cannabinoid laced on the plant material; this is true even within samplings of the same product.

Because they share pharmacological similarities with the Schedule I substance THC, the synthetic cannabinoids JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol pose substantial risks to the abuser. Numerous emergency department admissions have been connected to these substances, while law enforcement communications to DEA indicate multiple violent episodes linked to smoking these synthetic cannabinoids. Health warnings issued by numerous state public health departments and poison centers have described adverse health effects associated with smoking (inhaling) these products, including agitation, vomiting, tachycardia, elevated blood pressure, seizures, paranoia, hallucinations and non-responsiveness, and fatality.

Case reports describe presentations to emergency departments of individuals exposed to synthetic cannabinoids with symptoms that include anxiety and panic attacks, tremors, generalized convulsions, psychosis, heart palpitations and elevated pulse, severe gastrointestinal distress, tremors, blurred peripheral vision, nausea, and persistent vomiting with retching. Such abuse also includes instances of persons suspected of driving under the influence of these synthetic cannabinoids, including one incident where an automobile was driven through a residence. In that case the driver claimed to have no memory of the event while a toxicology analysis confirmed that the driver had smoked a product containing JWH-018, but not any other drugs.

7. Its Psychic or Physiological Dependence Liability: HHS states that the pharmacological profile of JWH-018, JWH-200, JWH-073, CP-47,497 and cannabicyclohexanol strongly suggests that they possess physiological and psychological dependence liability similar to that of the Schedule I controlled substances marijuana and THC. While no laboratory controlled clinical studies of the psychic or physical dependence potential of these five synthetic cannabinoids are currently available, their pharmacological profile indicates that the substances will have high psychic and physiologic dependence capacity.

Case reports have shown that herbal products containing synthetic cannabinoids could produce physical dependence and a withdrawal syndrome. The HHS analysis discusses one case report in which the authors concluded that the patient satisfied criteria for a diagnosis of DSM-IV and ICD-10 dependency syndrome on JWH-018. Some reported withdrawal symptoms included elevated blood pressure, restlessness, drug craving, nightmares, sweating, nausea, tremor and headache.

Because these substances act through the same molecular target as THC, the main active ingredient of marijuana, it can be reasonably expected that their physical dependence liability will be similar. Long-term, regular use of marijuana can lead to physical dependence and withdrawal following discontinuation as well as psychic addiction or dependence.

8. Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA: JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol are not considered immediate precursors of any controlled substance of the CSA as defined by Title 21, U.S.C § 802(23).

Conclusion: Based on consideration of the scientific and medical evaluations and accompanying recommendations of HHS, and based on DEA's consideration of its own eight-factor analyses, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of JWH-018, JWH-073, JWH-200, CP-47,497 and cannabicyclohexanol. As such, DEA hereby proposes to schedule JWH-018, JWH-073, JWH-200, CP-47,497 and cannabicyclohexanol as controlled substances under the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as Schedules I, II, III, IV, and V. The statute outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendations of the Assistant Secretary for Health of HHS and review of all available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(1), finds that:

(1) 1-pentyl-3-(1-naphthoyl)indole (JWH-018), 1-butyl-3-(1-naphthoyl)indole (JWH-073), 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200), 5-(1,1-dimethylheptyl)-2-(3-hydroxycyclohexyl)-phenol (CP-47,497), and 5-(1,1-dimethyloctyl)-2-(3-

hydroxycyclohexyl)-phenol (cannabicyclohexanol, CP-47,497 C8 homologue) have a high potential for abuse;

(2) 1-pentyl-3-(1-naphthoyl)indole (JWH-018), 1-butyl-3-(1-naphthoyl)indole (JWH-073), 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200), 5-(1,1-dimethylheptyl)-2-(3-hydroxycyclohexyl)-phenol (CP-47,497), and 5-(1,1-dimethyloctyl)-2-(3-hydroxycyclohexyl)-phenol (cannabicyclohexanol, CP-47,497 C8 homologue) have no currently accepted medical use in treatment in the United States; and

(3) there is a lack of accepted safety for use of 1-pentyl-3-(1-naphthoyl)indole (JWH-018), 1-butyl-3-(1-naphthoyl)indole (JWH-073), 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200), 5-(1,1-dimethylheptyl)-2-(3-hydroxycyclohexyl)-phenol (CP-47,497), and 5-(1,1-dimethyloctyl)-2-(3-hydroxycyclohexyl)-phenol (cannabicyclohexanol, CP-47,497 C8 homologue) under medical supervision.

Based on these findings, the Administrator of DEA concludes that 1-pentyl-3-(1-naphthoyl)indole (JWH-018), 1-butyl-3-(1-naphthoyl)indole (JWH-073), 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200), 5-(1,1-dimethylheptyl)-2-(3-hydroxycyclohexyl)-phenol (CP-47,497), and 5-(1,1-dimethyloctyl)-2-(3-hydroxycyclohexyl)-phenol (cannabicyclohexanol, CP-47,497 C8 homologue), including their salts, isomers and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, warrant control in Schedule I of the CSA (21 U.S.C. 812(b)(1)).

Requirements for Handling Five Synthetic Cannabinoids

If this rule is finalized as proposed, JWH-018, JWH-200, JWH-073, CP-47,497 and cannabicyclohexanol would be permanently, as they are currently temporarily, subject to the CSA and the Controlled Substances Import and Export Act (CSIEA) regulatory controls and

administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, and exporting of a Schedule I controlled substance, including the following:

Registration. Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with JWH-018, JWH-200, JWH-073, CP-47,497 or cannabicyclohexanols, or who desires to manufacture, distribute, dispense, import, export, engage in research or conduct instructional activities with any of the five synthetic cannabinoids, would need to be registered to conduct such activities pursuant to 21 U.S.C. 822 and 958 and in accordance with 21 CFR Part 1301.

Security. JWH-018, JWH-200, JWH-073, CP-47,497 or cannabicyclohexanol would be subject to Schedule I security requirements and would need to be manufactured, distributed, and stored pursuant to 21 U.S.C. 823 and in accordance with 21 CFR 1301.71, 1301.72(a), (c) and (d), 1301.73, 1301.74, 1301.75(a) and (c), 1301.76.

Labeling and Packaging. All labels and labeling for commercial containers of JWH-018, JWH-200, JWH-073, CP-47,497 or cannabicyclohexanol which are distributed on or after the effective date of the finalization of this rule would need to be in accordance with 21 CFR 1302.03-1302.07, pursuant to 21 U.S.C. 825.

Quotas. Quotas for JWH-018, JWH-200, JWH-073, CP-47,497 and cannabicyclohexanol will be established based on registrations granted and quota applications received pursuant to part 1303 of Title 21 of the Code of Federal Regulations.

Inventory. Every registrant required to keep records and who possesses any quantity of JWH-018, JWH-200, JWH-073, CP-47,497 or cannabicyclohexanol would be required to keep an inventory of all stocks of any of the five synthetic cannabinoids on hand pursuant to 21 U.S.C.

827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Every registrant who desires registration in Schedule I for any of the five synthetic cannabinoids would be required to conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants would be required to keep records pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23.

Reports. All registrants required to submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.33 would be required to do so regarding JWH-018, JWH-200, JWH-073, CP-47,497 and cannabicyclohexanol.

Order Forms. All registrants involved in the distribution of JWH-018, JWH-200, JWH-073, CP-47,497 or cannabicyclohexanol pursuant to 21 U.S.C. 828 would be required to comply with the order form requirements of 21 CFR 1305.

Importation and Exportation. All importation and exportation of JWH-018, JWH-200, JWH-073, CP-47,497 or cannabicyclohexanol would need to be done in accordance with 21 CFR Part 1312, pursuant to 21 U.S.C. 952, 953, 957, and 958.

Criminal Liability. Any activity with JWH-018, JWH-200, JWH-073, CP-47,497 or cannabicyclohexanol not authorized by, or in violation of, Subchapter I Part D and Subchapter II of the CSA or the CSIEA occurring on or after effective date of the finalization of this proposed rule would be unlawful.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures done “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for

scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to Section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988

This proposed regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132

This proposed rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Executive Order 13175

This proposed rule will not have tribal implications and will not impose substantial direct compliance costs on Indian tribal governments.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501-3521.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR Part 1308 is proposed to be amended as follows:

PART 1308— SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR Part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

2. Section 1308.11 is amended by redesignating paragraphs (d)(18) through (35) as paragraphs (d)(19) through (36) and adding a new paragraph (d)(18) to read as follows:

§ 1308.11 Schedule I.

* * * *

(d) * * *

(18) Cannabimimetic agents

(i) 1-Butyl-3-(1-naphthoyl)indole (Other names: JWH-073) 7173

(ii) 5-(1,1-Dimethylheptyl)-2-(3-hydroxycyclohexyl)-phenol (Other names: CP-47,497)
..... 7297

(iii) 5-(1,1-Dimethyloctyl)-2-(3-hydroxycyclohexyl)-phenol (Other names:
cannabicyclohexanol and CP-47,497 C8 homologue) 7298

(iv) 1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (Other names: JWH-200)
..... 7200

(v) 1-Pentyl-3-(1-naphthoyl)indole (Other names: JWH-018 and AM678)... 7118

* * * *

Dated:
February 24, 2012

Michele M. Leonhart
Administrator

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